

**ATTACHMENT #1
TO THE PERFORMANCE WORK STATEMENT (PWS)**

QA Requirements and Definitions

EPA's Quality System Website: <http://www.epa.gov/quality/>

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The QAPP shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

Definitions:

Environmental Data - These are any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, that are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2 - EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001,
<http://www.epa.gov/quality/qs-docs/r2-final.pdf>

R-5 - EPA Requirements for QA Project Plans (EPA/240/B-01/003) March, 2001
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Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Quality System Specifications:

- (1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;
- (2) an organizational chart showing the position of the QA function;
- (3) delineation of the authority and responsibilities of the QA function;
- (4) the background and experience of the QA personnel who will be assigned to the project; and
- (5) the organization's general approach for accomplishing the QA specifications in the PWS.

Category Level Designations (determines the level of QA required):

- **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in R-5.
- **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in R-5.
- **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of R-5, as outlined in the QAPP requirements for the specific project type (see below).
- **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of R-5, as outlined in the QAPP requirements for the specific project type (see below).

Guidance for QAPPs by Project Type (described in more detail on subsequent pages):

These outlines of QAPP Requirements for various project types are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario, and QAPPs must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

- **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. Additional guidance is given in “QAPP Requirements for Applied Research Projects”.
- **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. Additional guidance is given in “QAPP Requirements for Basic Research Projects”.
- **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to engineering projects involving environmental technologies, an all inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Comprehensive guidance can be found in the EPA Quality System document “Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation” G-11, at <http://www.epa.gov/quality/qs-docs/g11-final-05.pdf>.
- **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. Additional guidance is given in “QAPP Requirements for Method Development Projects”.
- **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. Comprehensive guidance is provided in the EPA Quality System document “Guidance for Quality Assurance Project Plans for Modeling” G-5M, <http://www.epa.gov/quality/qs-docs/g5m-final.pdf>. Abbreviated guidance is provided in “QAPP Requirements for Research Model Development and Application Projects”.
- **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. Additional guidance is given in “QAPP Requirements for Sampling and Analysis Projects”.

- **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. Additional guidance is given in “QAPP Requirements for Secondary Data Projects”.
- **Software Development Project** - pertains to projects dealing with software development or data management and includes all types of software/hardware systems development, data base design and maintenance, and data validation and verification systems. Additional guidance is given in “QAPP Requirements for Software and Data Management Projects”.

NHSRC QUALITY ASSURANCE REQUIREMENTS FORM*Attachment 1 to the Statement of Work*

I GENERAL INFORMATION

Title: Determination of the persistence of non-spore-forming biological threat agents in the environment

Description: Laboratory Study to determine persistence of select agents over time on environmental substrates

Project ID: HS4.03.01

Status: Original

Number Ammended:

QA Category: III

Action Type: Extramural

Peer Review Category: III

Security Classification: Unclassified

Project Type: Sampling and Analysis

QAPP Status 1: Not Delivered

QAPP Status 2: Not Applicable

QAPP Status 3: Not Applicable

Vehicle Status: New Vehicle

Vehicle Type: Contract

*If you are processing an **IAG** or **CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs in consultation with the QAMs in the various organizations must agree on, and document, which organization will take the lead for QA, the names of the QAM and TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include this info in the IAG/CRADA package.*

II SCOPE OF WORK

Yes Does the Statement of Work contain the appropriate QA language?

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action. The contractor shall prepare a QAPP in accordance with the R-2 and R-5 and/or the attachments provided with the SOW. The QAPP must be approved prior to the start of any work. Additional information related to QA requirements can be found at <http://www.epa.gov/quality/qs-docs/r5-final.pdf>

Yes Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods?

(If "No" then skip to Section IV, and sign the form.)

No Will the SOW or any subsequent work assignments or task orders involve any cross-organizational efforts within EPA?

No Has a QAPP already been approved for the activities specified in the SOW?

No Is an applicable QAPP in the process of being prepared, revised, or approved by EPA personnel for future use by the contractor? (QA approval must be obtained before the contractor can start work.)

QAPP to be prepared after contract award

III QA DOCUMENTATION OPTIONS

All documentation specified under "Other" must be defined in the NHSRC Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW. (R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/qa_docs.html.)

Before Award Documentation

Not Applicable	Documentation of an organization's Quality System. QMP developed in accordance with:
Other	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract. Developed in accordance with: Explain: NHSRC QMP Programmatic QA Project Plan developed in accordance with:
Other	Application of QA and QC activities to the single project covered by contract. QA Project Plan developed in accordance with: Explain: NHSRC QMP

After Award Documentation

Not Applicable	Documentation of an organization's Quality System. QMP developed in accordance with:
Not Applicable	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract. Developed in accordance with:
Other	Documentation of the application of QA and QC activities to applicable project(s). Developed in accordance with: Explain: The QAPP shall be developed in accordance with NHSRC QMP and attachment #1
NHSRC QMP	Programmatic QA Project Plan with supplements for each specific project, developed in accordance with:
Not Applicable	Existing documentation of the application of QA and QC activities will be used:

IV SIGNATURE BLOCK

The signatures below verify that the Statement of Work (SOW) has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the COR understands these requirements, and that the COR will ensure that the quality requirements indicated on the previous pages of this form are incorporated into all associated SOWs. (Sign/date below, obtain a concurrence signature from the QA Staff, and submit the form along with the other extramural action documentation.)

Worth Calfee
NHSRC-DCMD Technical Lead Person

02/05/2014
Date

Eletha Roberts
NHSRC-IO QA Staff Member

02/05/2014
Date

QAPP REQUIREMENTS FOR SAMPLING AND ANALYSIS PROJECTS

(from Appendix B of the NHSRC QMP)

A sampling and analysis activity or project is typically defined as a study performed to generate data to either monitor parameters on a routine basis or to characterize a particular population for later studies. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT DESCRIPTION AND ORGANIZATION

- 1.1 The purpose of the study shall be clearly stated in the sampling and analysis plan (SAP).
- 1.2 Responsibilities and points of contact for each organization shall be identified in the SAP. This should include identification of key personnel and/or organization(s) responsible for sample collection and custody, analytical and/or process measurements, data reduction, report preparation, and quality assurance.

SECTION 2.0, SAMPLING

- 2.1 Sampling points for all measurements (*i.e.*, analytical, physical, and process, including locations and access points) shall be identified in the SAP whenever possible. If the specific locations cannot be identified at the time of plan generation, discuss the documentation and/or communication mechanism(s) for ensuring adequate information is captured to later identify sampling points.
- 2.2 The anticipated sampling frequency (*e.g.*, how many sampling events and how often events occur) and number of sample types (*e.g.*, metals, VOCs, SVOCs, *etc.*) taken at each event shall be provided.
- 2.3 The expected measurements (*i.e.*, specific analytes) planned for each sample type shall be summarized.
- 2.4 If applicable, known site-specific factors that may affect sampling procedures shall be described.
- 2.5 If applicable, any site preparation (*e.g.*, sampling device installation, sampling port modifications) needed prior to sampling shall be described.
- 2.6 Each sampling procedure to be used shall be discussed or referenced.
- 2.7 If compositing or splitting of samples is planned, the applicable procedures shall be described.
- 2.8 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.
- 2.9 Containers used for sample collection, transport, and storage for each sample type shall be described.
- 2.10 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*) shall be described.
- 2.11 Requirements for shipping samples shall be described.
- 2.12 Holding times requirements shall be noted.
- 2.13 Procedures for tracking samples in the laboratory and for maintaining chain_of_custody when samples are shipped shall be described. COC procedures shall be described to ensure that sample integrity is maintained (labeling, seals, records).
- 2.14 Information to be recorded and maintained by field personnel shall be discussed.

SECTION 3.0, TESTING AND MEASUREMENT PROTOCOLS

- 3.1 Each analytical method to be used shall be referenced. This includes EPA-approved and other validated nonstandard methods.
- 3.2 If applicable, modifications to EPA-approved or other validated nonstandard methods shall also be described.

SECTION 4.0, QA/QC CHECKS

- 4.1 The SAP shall list and define all QC checks and/or procedures used for the project, both field and laboratory as needed.
- 4.2 For each specified QC check or procedure, required frequencies and acceptance criteria shall be included.

SECTION 5.0, DATA REDUCTION AND REPORTING

- 5.1 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.
- 5.2 The reporting requirements (*e.g.*, units, reporting method [*e.g.*, wet or dry]) for each measurement and matrix shall be identified.

SECTION 6.0, REPORTING REQUIREMENTS

The deliverables expected from each organization responsible for field and/or analytical activities shall be described.

Attachment # 2

NHSRC QA To the Statement of Work Requirements/Definitions List

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These requirements typically pertain to single project efforts. The five specifications are:

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- ☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP QAPP requirements for the specific project type (see below).

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These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to

ensure that the data are of adequate quality and quantity to fit their intended purpose.

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- ☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at <http://www.epa.gov/quality/QS-docs/q5g-final-05.pdf>.
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Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NHSRC	National Homeland Security Research Center	QA	Quality Assurance
NRMRL	National Risk Management Research Laboratory	QAM	Quality Assurance Manager
QA ID	Quality Assurance Identification	QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan	SOW	Statement of Work
QS	Quality System	CRADA	Cooperative Research & Development Agreement
TLP	Technical Lead Person		

Attachment #2 to the Statement of Work
Revision 1. March 2006
NHSRC 06/02

**NHSRC QA
To the Performance Work Statement
Requirements/Definitions List**

Attachment # 1

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Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
<http://www.epa.gov/quality/QS-docs/r2-final.pdf>.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
<http://www.epa.gov/quality/QS-docs/r5-final.pdf>.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NHSRC	National Homeland Security Research Center	QA	Quality Assurance
NRMRL	National Risk Management Research Laboratory	QAM	Quality Assurance Manager
QA ID	Quality Assurance Identification	QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan	SOW	Statement of Work
QS	Quality System	CRADA	Cooperative Research & Development Agreement
TLP	Technical Lead Person		

**NHSRC QA
To the Performance Work Statement
Requirements/Definitions List**

Attachment # 1

EPA's Quality System Website: <http://www.epa.gov/quality>

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

EPA's Quality System Website: <http://www.epa.gov/quality/qs-docs/r5-final.pdf>

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

- (1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;**
- (2) an organizational chart showing the position of the QA function;**
- (3) delineation of the authority and responsibilities of the QA function;**
- (4) the background and experience of the QA personnel who will be assigned to the project; and**
- (5) the organization's general approach for accomplishing the QA specifications in the SOW.**

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):



Category I Project - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5."

- ☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.
- ☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).
- ☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

- ☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.
- ☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.
- ☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at <http://www.epa.gov/quality/QS-docs/g11-final-05.pdf>. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.
- ☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at <http://www.epa.gov/quality/QS-docs/q5g-final-05.pdf>.
- ☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.
- ☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M at <http://www.epa.gov/quality/QS-docs/q5m-final.pdf>.
- ☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.
- ☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.



Software Development and Data Management Project - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

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